INTERNATIONAL STANDARD

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Second edition 2017-02

Statistical methods in process management — Capability and performance —

Part 2:

Process capability and performance of time-dependent process models

Méthodes statistiques dans la gestion de processus — Aptitude et performance —

Partie 2: Aptitude de processus et performance des modèles de processus dépendants du temps





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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html

The committee responsible for this document is ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 4, *Applications of statistical methods in process management*.

This second edition of ISO 22514-2 cancels and replaces the corrected version of the first edition (ISO 22514-2:2013), of which it constitutes a minor revision.

The changes compared to the previous edition are as follows:

- the symbols and indices in C_{pk_I} , $C_{pk_{II}}$, P_{pk_I} and $P_{pk_{II}}$ have been improved;
- in <u>Table 2</u>, row "Location", column "C", the letter "s" has been replaced by "s/r";
- in <u>Table 2</u>, row "Location", column "D", the capital letter "S" has been replaced by "s/r";
- in <u>Table 3</u>, row "Location method label", rows "3" and "4" in Formulae (13) and (14) the usage of indices has been improved and it is more precise now;
- editorial adjustments have been made to comply with the latest edition of the ISO/IEC Directives, Part 2, 2016.

A list of all parts in the ISO 22514- series, published under the general title *Statistical methods in process management* — *Capability and performance*, can be found on the ISO website.

Introduction

Many standards have been created concerning the quality capability/performance of processes by international, regional and national standardization bodies and also by industry. All of them assume that the process is in a state of statistical control, with stationary, normally distributed processes. However, a comprehensive analysis of production processes shows that, over time, it is very rare for processes to remain in such a state.

In recognition of this fact, this document provides a framework for estimating the quality capability/performance of industrial processes for an array of standard circumstances. These circumstances are categorized based on the stability of the mean and variance, as to whether they are constant, changing systematically, or changing randomly. As such, the quality capability/performance can be assessed for very differently shaped distributions with respect to time.

In other parts of ISO 22514 more detailed information about calculations of indices can be found. It should be noted that where the capability indices given in this document are computed they only form point estimates of their true values. It is therefore recommended that wherever possible the indices' confidence intervals are computed and reported.

Statistical methods in process management — Capability and performance —

Part 2:

Process capability and performance of time-dependent process models

Scope

This document describes a procedure for the determination of statistics for estimating the quality capability or performance of product and process characteristics. The process results of these quality characteristics are categorized into eight possible distribution types. Calculation formulae for the statistical measures are placed with every distribution.

The statistical methods described in this document only relate to continuous quality characteristics. They are applicable to processes in any industrial or economical sector.

This method is usually applied in case of a great number of serial process results, but it can also be used for small series (a small number of process results).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5479, Statistical interpretation of data — Tests for departure from the normal distribution

Terms definitions, symbols and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO 3534-2 and ISO 22514-1, and the symbols and abbreviated terms given below, apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1 Symbols

process capability index $C_{\mathfrak{p}}$

 C_{pk} minimum process capability index

lower process capability index $C_{\mathrm{pk}_{I}}$

upper process capability index C_{pk_U}

constant based on subgroup size n C4

ISO 22514-2:2017(E)

 Δ dispersion of the process

 $\Delta_{\rm L}$ difference between $X_{\rm mid}$ and $X_{0,135}$ % of the distribution of the product characteristic

 $\Delta_{\rm U}$ difference between $X_{99.865}$ % and $X_{\rm mid}$ of the distribution of the product characteristic

 d_2 constant based on subgroup size n

k number of subgroups of the same size *n*

 μ average location of the process

L lower specification limit

 $M_{l,d}$ calculation methods with location method label l and dispersion method label d

N sample size

 p_L lower fraction nonconforming

*p*_t total fraction nonconforming

 p_U upper fraction nonconforming

 $P_{\rm p}$ process performance index

 P_{vk} minimum process performance index

 $P_{\mathrm{pk}_{I}}$ lower process performance index

pk_L

 $P_{\mathrm{pk}_{I\!I}}$ upper process performance index

 R_i range of the *i*th subgroup

s standard deviation, realized value

 σ standard deviation, population

S standard deviation, sample statistic

 S_i observed sample standard deviation of the *i*th subgroup

S_t standard deviation, with the subscript "t" indicating total standard deviation

U upper specification limit

 $X_{0,135\%}$ 0,135 % distribution quantile

*X*99,865 % distribution quantile

 $X_{50\%}$ 50 % distribution quantile

 $X_{\rm mid}$ distribution midpoint

3.2 Abbreviated terms

ANOVA analysis of variance

SPC statistical process control

4 Process analysis

The purpose of process analysis is to obtain knowledge of a process. This knowledge is necessary for controlling the process efficiently and effectively so that the products realized by the process fulfil the quality requirement. It is a general assumption of this document that a process analysis has been carried out and subsequent process improvements have been implemented.

The behaviour of a characteristic under consideration can be described by the distribution, the location, the dispersion and the shape, parameters of which are time-dependent functions, in general. Different models of such resulting distributions the parameters of which are time-dependent functions are discussed in <u>Clauses 6</u> and <u>7</u>. To indicate whether a time-dependent distribution model fits, statistical methods [e.g. estimating parameters, analysis of variance (ANOVA)] including graphical tools (e.g. probability plots, control charts) are used.

The values of the characteristics under consideration are typically determined on the basis of samples taken from the process flow. The sample size and frequency should be chosen depending on the type of process and the type of product so that all important changes are detected in time. The samples should be representative for the characteristic under consideration. To asses the stability of the process a control chart should be used. Information on the use of control charts can be found in ISO 7870-2.

5 Time-dependent distribution models

The instantaneous distribution characterizes the behaviour of the characteristic under investigation during a short interval. Usually, it is the time interval during which the sample (e.g. the subgroup) can be taken from the process. Observing the process continuously in time for a longer time interval the output from the process is called the resulting process distribution and it is described by a corresponding time-dependent distribution model that reflects

- the instantaneous distribution of the characteristic under consideration, and
- the changes of its location, dispersion and shape parameters during the time interval of process observation.

In practice, the resulting distribution can be represented by the whole data set, e.g. when SPC is applied, by all subgroups gained during the interval of the process observation.

Time-dependent distribution models can be classified into four groups according to whether the location and dispersion moments are constant or changing (see <u>Table 1</u>).

- a) A process whose location and dispersion are constant is in time-dependent distribution model A. In this case only, all the means and variances of the instantaneous distributions are equal to each other and they are equal to the resulting distribution.
- b) If the dispersion of a process is changing with time, but the location stays constant, the process is said to be in time-dependent distribution model B.
- c) If the dispersion is constant, but the location is changing, we have time-dependent distribution model C.
- d) Otherwise, we have time-dependent distribution model D.

 ${\bf Table~1-Classification~of~time-dependent~distribution~models}$

Process-standard	Process average $\mu(t)$										
deviation s(t)	Constant			Not constant							
		I	A		С						
		A1	A2		C1	C2	С3	C4			
			Not	Location	Random	Random	Systematic	Systematic and random			
Constant							(e.g. trend)	(e.g. lot to lot)			
Constant	Short time	Normal distributed	normal distributed	Short time distribu- tion	Normal distributed	Normal distributed	Normal distributed	Normal distributed			
	distribution		– unimodal	Resulting distribution	Normal distributed	Not normal distrib- uted - unimodal	Any shape	Any shape (e.g. multimodal)			
Not	Resulting	B Any shape – unimodal		Doculting distribution	D						
constant	distribution			Resulting distribution	Any shape						

For changing moments, the models can be classified according to whether the changes are random, systematic or both.

NOTE Model A2 is known as *stationary* in time-series analysis literature and model A1 is known as *second* order stationary.

<u>Table 2</u> summarizes the basic features of individual time-dependent distribution models; their graphical representations are given in <u>Figures 1</u> to <u>8</u>. There are subclasses of time-dependent distribution models A and C which are introduced due to their practical importance. They differ in the shape of the resulting distribution and in the cause of the process being in an out-of-control state.

Table 2 — Basic features of time-dependent distribution models

Characteristic	Time-dependent distribution modelsa								
Characteristic	A1	A2	В	C1	C2	С3	C4	D	
Location	С	С	С	r	r	S	s/r	s/r	
Dispersion	С	С	s/r	С	С	С	С	s/r	
Instantaneous distribution	nd	1m	nd	nd	nd	as	as	as	
Resulting distribution	nd	1m	1m	nd	1m	as	as	as	
Figure	1	2	3	4	5	6	7	8	

Location/dispersion:

- c parameter remains constant
- r parameter changes randomly only
- s parameter changes systematically only

Instantaneous/resulting distribution:

nd normally distributed

1m not normally distributed, one mode only

as any shape

a The choice of the model is a result of process analysis.

For each time-dependent distribution model, several instantaneous distributions are shown as a function of time; the related resulting distribution is shown as well. These distributions are not drawn to scale.

The choice of models and their verification requires extensive data analysis. This will usually require the use of statistical software.

Time-dependent distribution model A1 (see <u>Figure 1</u>) has the following characteristics (e.g. the measured length of an item from a process in a state of statistical control):

- location: constant:
- dispersion: constant;
- instantaneous distribution: normally distributed;
- resulting distribution: normally distributed.

This process is under statistical control.

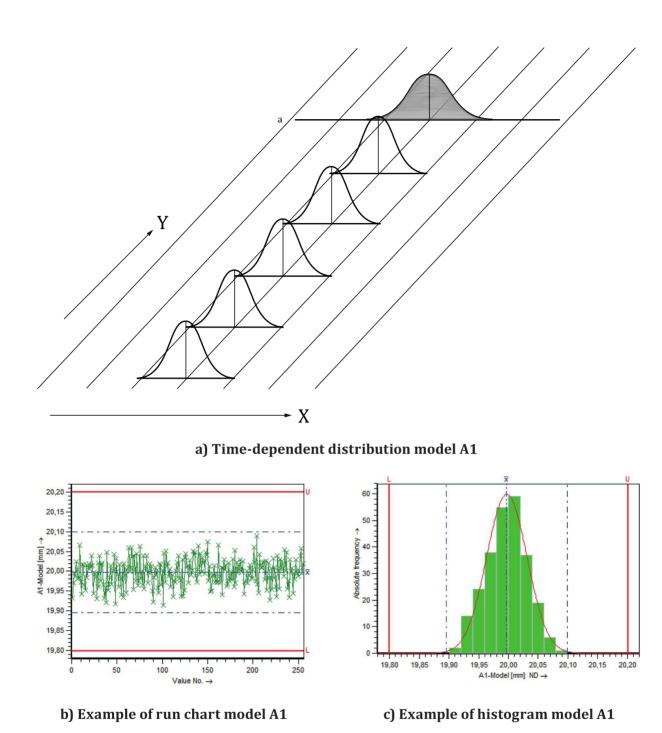


Figure 1 — Graphical representation of time-dependent distribution model A1

Y time

Time-dependent distribution model A2 (see <u>Figure 2</u>) has the following characteristics (e.g. the surface roughness of an item as an example for a physically limited characteristic):

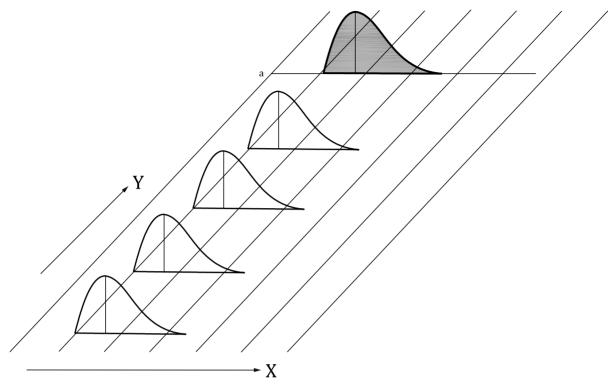
location: constant;

X characteristic value

- dispersion: constant;
- instantaneous distribution: not normally distributed, unimodal;
- resulting distribution: not normally distributed, unimodal.

Key

Resulting distribution.



a) Time-dependent distribution model A2

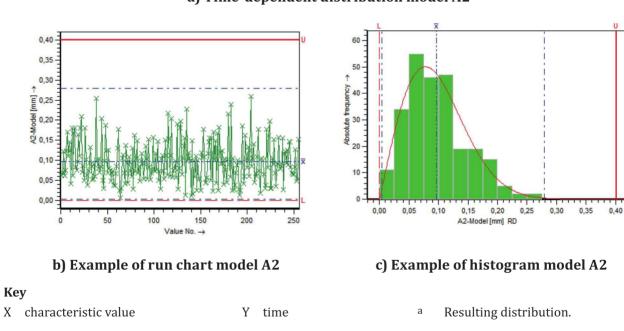


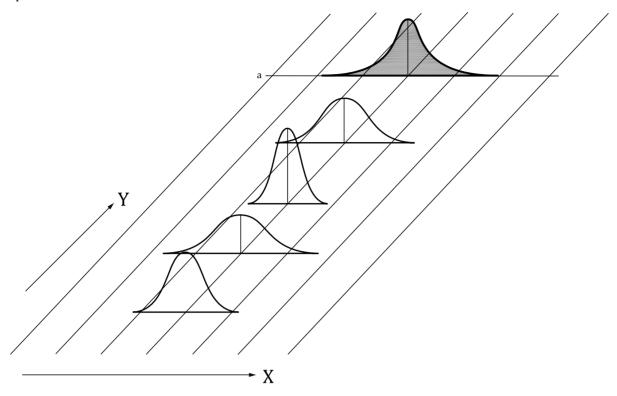
Figure 2 — Graphical representation of time-dependent distribution model A2

Time-dependent distribution model B (see <u>Figure 3</u>) has the following characteristics (e.g. different wear of the spindles on a multiple-spindle automatic machine with equal centring):

- location: constant;
- dispersion: systematic or random variation;
- instantaneous distribution: normally distributed;

resulting distribution: not normally distributed, unimodal.

This process is not under statistical control.



a) Time-dependent distribution model B

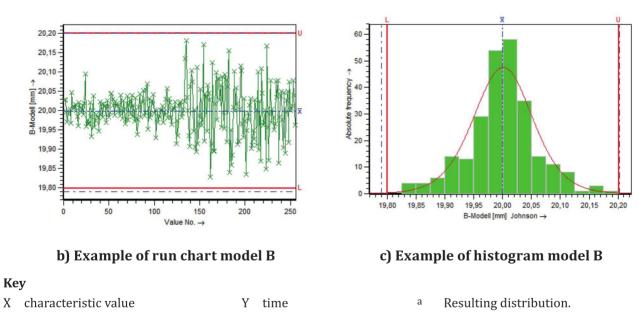
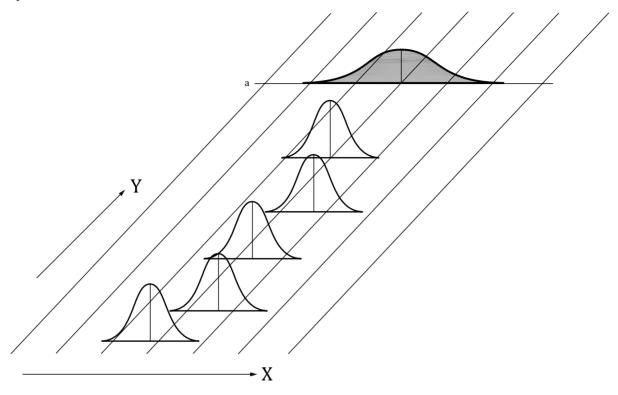


Figure 3 — Graphical representation of time-dependent distribution model B

Time-dependent distribution model C1 (see <u>Figure 4</u>) has the following characteristics (e.g. different centring of workholding fixtures):

- location: random (normally distributed);
- dispersion: constant;

- instantaneous distribution: normally distributed;
- resulting distribution: normally distributed.



a) Time-dependent distribution model C1

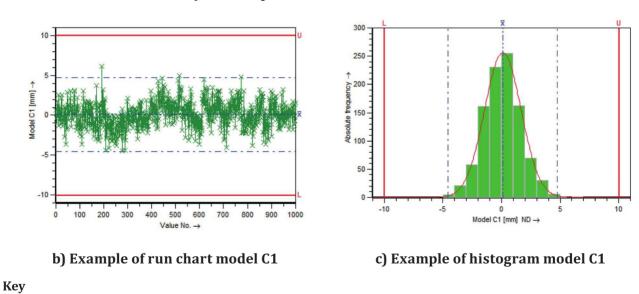


Figure 4 — Graphical representation of time-dependent distribution model C1

Y time

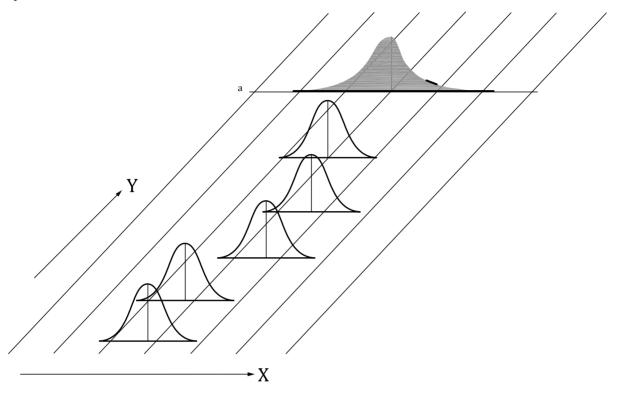
Time-dependent distribution model C2 (see Figure 5) has the following characteristics (e.g. fixed tools):

- location: random (not normally distributed, unimodal);
- dispersion: constant;

X characteristic value

Resulting distribution.

- instantaneous distribution: normally distributed;
- resulting distribution: not normally distributed, unimodal.



a) Time-dependent distribution model C2

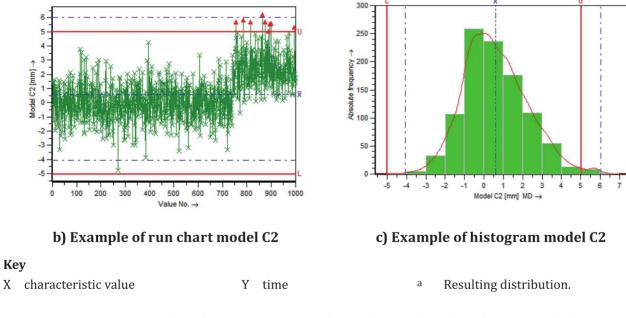
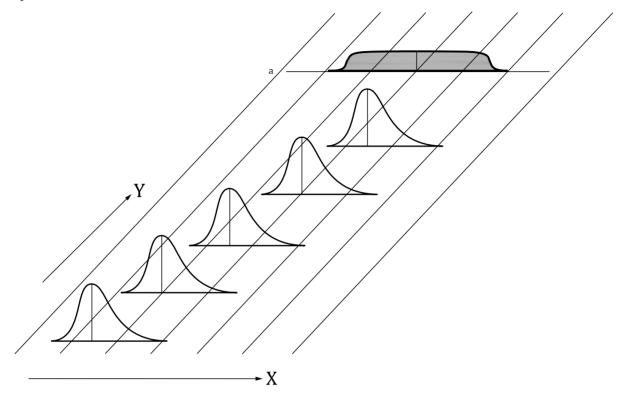


Figure 5 — Graphical representation of time-dependent distribution model C2

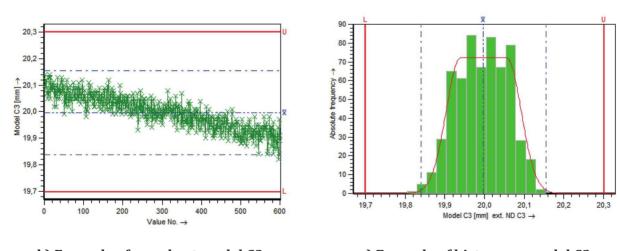
Time-dependent distribution model C3 (see Figure 6) has the following characteristics:

- location: function oriented (e.g. trend, caused by wear, and cycle);
- dispersion: constant;

- instantaneous distribution: any shape whatever;
- resulting distribution: any shape whatever.



a) Time-dependent distribution model C3



b) Example of run chart model C3

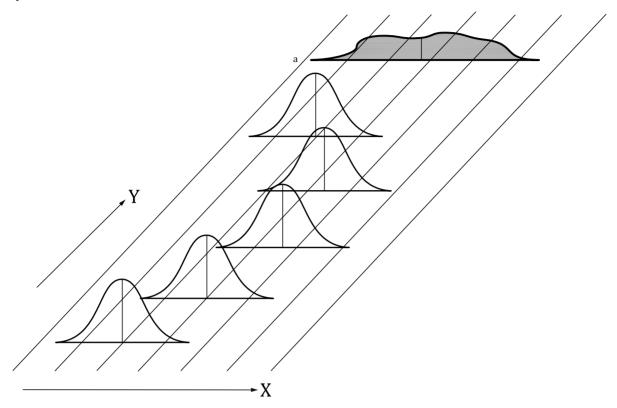
c) Example of histogram model C3

 $Figure\ 6-Graphical\ representation\ of\ time-dependent\ distribution\ model\ C3$

Time-dependent distribution model C4 (see Figure 7) has the following characteristics:

- location: systematic and random change (e.g. tool changes or change of batches);
- dispersion: constant;

- instantaneous distribution: any shape whatever;
- resulting distribution: any shape whatever.



a) Time-dependent distribution model C4

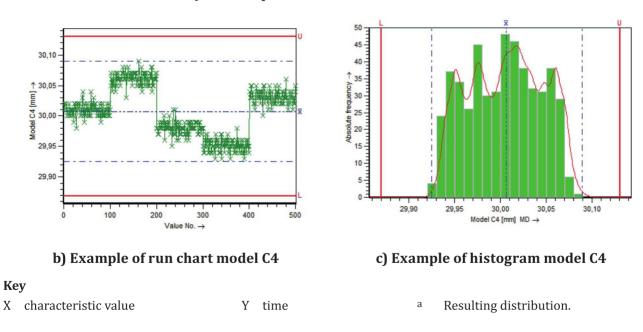
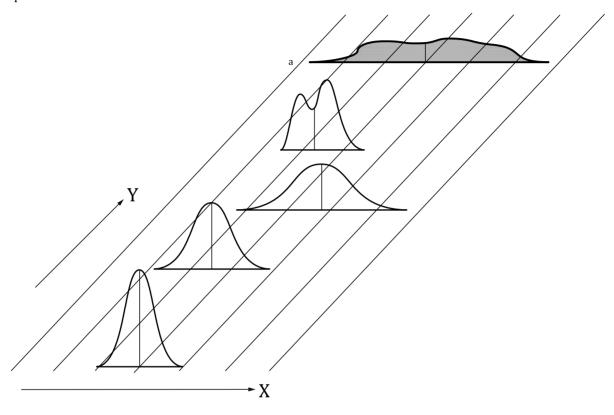


Figure 7 — Graphical representation of time-dependent distribution model C4

Time-dependent distribution model D (see Figure 8) has the following characteristics (e.g. multi-stream processes):

location: systematic and random change;

- dispersion: systematic and random change;
- instantaneous distribution: any shape whatever;
- resulting distribution: any shape whatever.



a) Time-dependent distribution model D

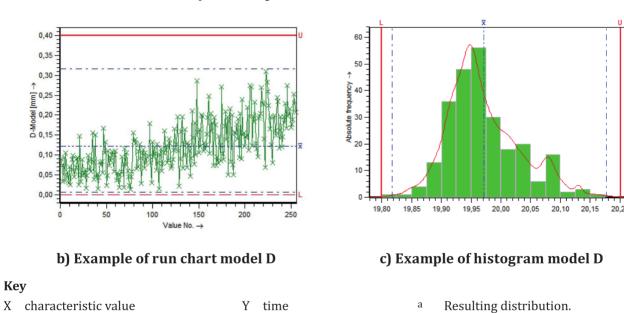


Figure 8 — Graphical representation of time-dependent distribution model D

6 Process capability and performance indices

6.1 Methods for determination of performance and capability indices — Overview

6.1.1 General

As detailed in the preceding clauses, the basis for determination of process capability and performance statistics is the distribution of characteristic values of a product characteristic.

The calculation of the performance indices, as well as the capability indices is based on the location and dispersion of characteristic values with respect to the tolerance.

A general graphical representation is shown in Figure 9.

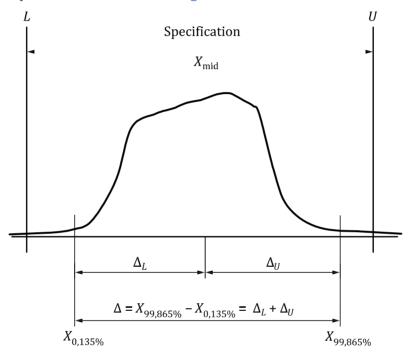


Figure 9 — Graphical representation of the general geometric method

In Figure 9, $X_{\rm mid}$ indicates the location of the process and Δ indicates the dispersion of the process. Their exact definitions, depending on the method, will be given later. The dispersion is bounded by the lower reference limit $X_{0.135}$ %, and the upper reference limit $X_{9.865}$ %. Then we have

$$\Delta_L = X_{\text{mid}} - X_{0.135\%} \tag{1}$$

and

$$\Delta_U = X_{99.865\%} - X_{\text{mid}} \tag{2}$$

The process performance indices are defined by ratios of length of a geometric parameter of the distribution to the specified tolerance.

Process performance index:

$$P_{\rm p} = \frac{U - L}{\Delta} \tag{3}$$

Lower process performance index:

$$P_{\text{pk}_L} = \frac{X_{\text{mid}} - L}{\Delta_L} \tag{4}$$

Upper process performance index:

$$P_{\text{pk}_U} = \frac{U - X_{\text{mid}}}{\Delta_U} \tag{5}$$

Minimum process performance index:

$$P_{\text{pk}} = \min\left(P_{\text{pk}_L}, P_{\text{pk}_U}\right) \tag{6}$$

If a process is shown to be in the state of statistical control, a capability index can be assigned. The formulae are the same as for the corresponding performance index.

Capability index:

$$C_{\rm p} = \frac{U - L}{\Lambda} \tag{7}$$

Lower capability index:

$$C_{\text{pk}_L} = \frac{X_{\text{mid}} - L}{\Delta_L} \tag{8}$$

Upper capability index:

$$C_{\text{pk}_{U}} = \frac{U - X_{\text{mid}}}{\Delta_{U}} \tag{9}$$

Minimum capability index:

$$C_{\rm pk} = \min\left(C_{\rm pk_{I}}, C_{\rm pk_{II}}\right) \tag{10}$$

There are different estimators for the location, μ , and the dispersion, Δ , of a given data set.

IMPORTANT — It should be emphasized that a quantitative comparison of the performance or capability indices calculated according to the different methods is not meaningful and should not be done.

6.1.2 Calculation of location

The location of the process, X_{mid} , can be calculated using one of the formulae given in Table 3.

Table 3 — Different methods for calculation of location

Location method label, l	Calculation method of location/Formula $\mathrm{M}_{l,d}$					
1	$\widehat{X}_{\text{mid}} = \overline{x} = \frac{1}{k \cdot n} \sum x_i$	(11)				
2	$\hat{X}_{\text{mid}} = \tilde{x} = X_{50\%} = \begin{cases} x \left(\frac{n+1}{2}\right) & ; n \text{ odd} \\ \frac{1}{2} \left[x \left(\frac{n}{2}\right)^{+} x \left(\frac{n}{2}+1\right)\right] & ; n \text{ even} \end{cases} $ order statistic x_i	(12)				
3	$\hat{X}_{\text{mid}} = \overline{\overline{x}} = \frac{1}{k} \sum_{j=1}^{k} \overline{x}_{j}$	(13)				
4	$\hat{X}_{\text{mid}} = \overline{\tilde{x}} = \frac{1}{k} \sum_{j=1}^{k} \tilde{x}_{j}$	(14)				

 x_i individual values

6.1.3 Calculation of dispersion

The dispersion of the process can be calculated using one of the formulae given in Table 4.

n number of values

 $[\]left| \overline{x}_{j} \right|$ average of the jth subgroup

k number of subgroups of size n

 $[\]tilde{x}_j$ median of the jth subgroup

Dispersion method label, d	Calculation method of dispersion/Formula M_{bd}	No.
1	$\hat{\Delta} = X_{99,865\%} - X_{0,135\%};$ $\hat{\Delta}_U = X_{99,865\%} - X_{\text{mid}}; \hat{\Delta}_L = X_{\text{mid}} - X_{0,135\%}$	(15)
2	$\hat{\Delta} = 6\hat{\sigma}; \hat{\Delta}_U = 3\hat{\sigma}; \hat{\Delta}_L = 3\hat{\sigma}$ where $\hat{\sigma} = \sqrt{\frac{\sum s_i^2}{k}}$	(16)
3	$\hat{\Delta} = 6\hat{\sigma}; \hat{\Delta}_U = 3\hat{\sigma}; \hat{\Delta}_L = 3\hat{\sigma}$ where $\hat{\sigma} = \frac{\sum s_i}{k \cdot c_4}$	(17)
4	$\hat{\Delta} = 6\hat{\sigma}; \hat{\Delta}_U = 3\hat{\sigma}; \hat{\Delta}_L = 3\hat{\sigma}$ where $\hat{\sigma} = \frac{\sum R_i}{k \cdot d_2}$	(18)
5	$\hat{\Delta} = 6\hat{\sigma}; \hat{\Delta}_U = 3\hat{\sigma}; \hat{\Delta}_L = 3\hat{\sigma} \text{where } \hat{\sigma} = s_t = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} (x_i - \bar{x})^2}$	(19)

Table 4 — Different methods for calculation of dispersion

See ISO 7870-2 for tables of c_4 and d_2 coefficients.

 $M_{l,d}$ is used as a symbol for the calculation method. The subscript l refers to an equation for calculation of the estimator for the location μ [Formulae (11) to (14)]. The subscript d refers to an equation for calculation of the estimator for the dispersion Δ [Formulae (15) to (19)].

6.1.4 Calculation of $X_{0.135}$ % and $X_{99.865}$ %

The three procedures that can be used to estimate the $X_{0.135}$ % and $X_{99.865}$ % are the following.

- a) Fit a distribution to the combined data set, and estimate them from the fitted resulting distribution.
- b) Estimate them directly from the combined data set. In order to obtain reliable estimate of $X_{0,135\%}$ and $X_{99,865\%}$ in this procedure, the size of the given data set must be large. For instance, for a combined sample sizes of 1 000, $X_{0,135\%}$ and $X_{99,865\%}$ are taken to be the minimum and maximum value of the data set.
- c) Estimate them from a probability plot in accordance to ISO 5479). If the data do not form a normal distribution it may become necessary to employ a different worksheet.

The symbol for the calculation of an index should be $M_{l,d}$, where l defines the calculation method for location and d defines the calculation method for the dispersion.

EXAMPLE The calculation method $M_{1,2}$ is based on calculation of average and variance.

- The estimator $\hat{\Delta}$ for d=1 is the most general one, it may be used under all conditions.
- The estimators Δ for d = 2, 3 and 4 estimate the subgroup spread only. They should be used for process model A1 only because they neglect the differences between subgroups.

 s_i^2 variance of the *i*th subgroup

 s_i standard deviation of the ith subgroup

k number of subgroups of size n

 R_i range of the *i*th subgroup

 s_t standard deviation of the whole data set

— The estimators $\hat{\Delta}$ for d = 2, 3, 4 and 5 assume that the data are normally distributed. Otherwise, their result is biased depending on the type of distribution.

NOTE Δ is also called the *reference interval*.

6.2 One-sided specification limits

One-sided specification limits can be treated in the same manner as two-sided specification limits. See Figure 10.

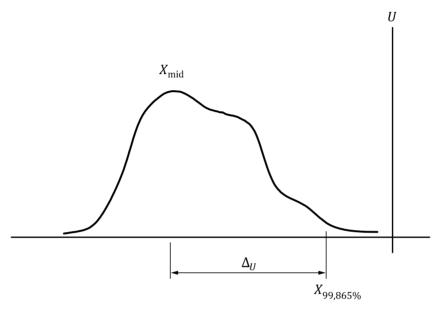


Figure 10 — Graphical representation of the calculation method ΔU

In the case of an upper specification limit, we have the following.

Upper process performance index:

$$P_{\text{pk}_U} = \frac{U - X_{\text{mid}}}{\Delta_U} \tag{16}$$

Minimum process performance index:

$$P_{\rm pk} = P_{\rm pk_{II}} \tag{17}$$

If a process is proven to be in the state of statistical control, a capability index can be assigned. The formulae are the same as for the corresponding performance index.

Upper capability index:

$$C_{\text{pk}_{U}} = \frac{U - X_{\text{mid}}}{\Delta_{U}} \tag{18}$$

Minimum capability index:

$$C_{\rm pk} = C_{\rm pk_{II}} \tag{19}$$

 $X_{99,865}$ % and X_{mid} are estimated as in method M_{2,1}. See Figure 11.

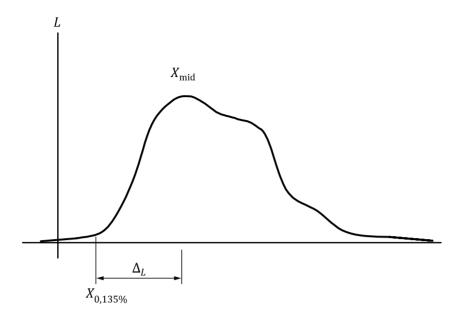


Figure 11 — Graphical representation of calculation method Δ_L

In the case of a lower specification limit, we have the following.

Lower process performance index:

$$P_{\text{pk}_L} = \frac{X_{\text{mid}} - L}{\Delta_L} \tag{20}$$

Minimum process performance index:

$$P_{\text{pk}} = P_{\text{pk}_L} \tag{21}$$

If a process is proven to be in the state of statistical control, a capability index can be assigned. The formulae are the same as for the corresponding performance index.

Lower capability index:

$$C_{\text{pk}_L} = \frac{X_{\text{mid}} - L}{\Delta_L} \tag{22}$$

Minimum capability index:

$$C_{\mathrm{pk}} = C_{\mathrm{pk}_L} \tag{23}$$

 $X_{0,135}$ % and X_{mid} are estimated as in method M_{2,1}.

6.3 Use of different calculation methods

For a specific time-dependent distribution model not all calculation methods can be used. <u>Table 5</u> shows the combination of models and calculation methods.

Table 5 — Process capability indices

	Time model	A1	A2	В	C1	C2	С3	C4	D
	1	а		a					
Location calculation	2	a	а	а	а	a	а	а	a
Location calculation	3	а							
	4	a	а	а					
	1	а	а	а	а	а	а	а	а
	2	a							
Dispersion calculation	3	а							
	4	а							
	5	а	а	а	а				а
a Indicates those methods which could be used for the calculation of indices.									

7 Reporting process performance/capability indices

If process performance/capability statistics are used for process qualification, they shall be reported with relation to this document. The calculation methods for location and dispersion and the number of values used as basis for the calculation and also the measurement uncertainty shall be stated.

Other information may be added, including

- frequency of sampling,
- time and duration of data taking; choice of time distribution model justification, and
- technical conditions (batches, operation, tools).

An example is given in <u>Table 6</u>.

Table 6 — Example of report of calculated process capability indices

Process performance/capability index	$C_{\rm p}$ = 1,68				
Minimum process performance/capability index	$C_{\rm pk} = 1,47$				
Calculation method	M _{1,1}				
Number of values used for the calculation	2 000				
Measurement uncertainty	0,002 mm				
Time distribution model	A1				
Calculation method M _{1.1} means that the canability calculation is done using the average and the reference interval as					

Calculation method $M_{1,1}$ means that the capability calculation is done using the average and the reference interval as estimators for location and dispersion.

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